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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,611	08/26/2008	Steven Siegel	P-7562-US	7210

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EXAMINER	
AL-AWADI, DANAH J	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
09/20/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@pczlaw.com
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Office Action Summary	Application No.	Applicant(s)	
	10/585,611	SIEGEL ET AL.	
	Examiner	Art Unit	
	DANAH AL-AWADI	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-45* is/are pending in the application.

5a) Of the above claim(s) *21-45* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-20* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS OF THE APPLICATION

1. Receipt is acknowledged of Applicants' amendments and remarks filed 08/17/2011.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/17/2011 has been entered.

INFORMATION DISCLOSURE STATEMENT

2. No Information Disclosure Statement (IDS) has been submitted for review.

WITHDRAWN OBJECTIONS/REJECTIONS

3. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

MAINTAINED REJECTIONS

CLAIM REJECTIONS - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence

Claims 1-13 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel et al. (US 2002/0179096) in view of Kino et al. (US Patent 5, 871, 778).

Siegel et al. teaches a surgically implantable drug delivery system for long-term delivery of the antipsychotic drug – haloperidol (see Abstract); (page 2, paragraphs 0019-0021). The implantable delivery system contains a biodegradable polymer, preferably a lactide-glycolide copolymer (page 1, paragraph 0002); (page 3, paragraph 0023). Siegel et al. discloses an implant of polylactide-co-glycolide, one phase of which has slow release, the other having a faster release (paragraph 0024). The implant is specifically indicated for the treatment of psychotic disorders ((paragraph 0021) and (0032)). The implantable delivery system comprising the antipsychotic drug haloperidol provides superior treatment outcomes due to improved medication adherence. The implants are designed to last for months to years. Advantages of the implants include lower dosing, steady state serum drug levels and increased bioavailability (page 2, paragraph 0022). The implants can be removed and thus offers a degree of reversibility (page 1, paragraph 0010).

It is noted that Siegel does not teach their implant to be a "rod-shaped" structure. However, the particular shape of the implant would be based on personal preference and/or the particular intended use of the implant. Moreover, an effective shape can be determined by one of ordinary skill in the art in order to provide an optimal outcome. The particular shape of the implant being claimed does not render a patentable distinction over the disclosure of Siegel who clearly recognizes and teaches an implantable drug delivery system comprising an antipsychotic drug (haloperidol) in combination with biocompatible polymers, such as polylactic acid and polyglycolic acid, whereby the implant is removable and is effective for the treatment of psychotic disorders and conditions.

Thus, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art, given the teachings of Siegel.

It would have been obvious to the skilled artisan at the time the invention was made to have administration of two formulations because it is routine in the art to administer drugs to the same patient in multiple different dosage forms in order to achieve a particular therapeutic effect.

With regards to the limitations "whereby administering said first and second formulation results in therapeutic circulating levels of said drug, for a period of about 14-120 days, thereby being a method of treating a nervous system disorder", until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the drug formulation which is instantly claimed. Furthermore, the limitation having circulating therapeutic levels of the drug is future intended use as a result of the composition being implanted and is given little patentable weight. Absent evidence to the contrary, it is expected that the formulation would achieve the same circulating levels as claimed.

Siegel teaches subcutaneous delivery (paragraph (0013)). Furthermore, Siegel teaches implantable drug delivery devices (abstract). These devices are fully capable of being implanted subcutaneously.

Siegel teaches that the implant comprises a PLGA (polylactic acid to polyglycolic acid) ratio of 75:25 (paragraph (0024)). Therefore, as per pending claim 9, the implants vary in terms of drug concentration, polymer composition, or combination thereof. Siegel also teaches the biodegradable polymer also comprises about 50 to 100% polylactide and 0 to 50% polyglycolide (paragraph (0023)). The range reads and falls within the range of said polymer 40-90%. The drug, haloperidol is disclosed to be in the preferred range of from about 20% to about 40% (paragraph (0023)). Also see Examples 4-5. This range reads on the range of therapeutic drug of 10-60%.

Siegel teaches that the therapeutic drug is present in an amount of 30%-60% of the mass of the implant (paragraph (0023)).

With regards to administration of the formulations, it would have been obvious to one of ordinary skill in the art to administer the formulation within 1-24 hours, cyclically, or within 160-200 days in order to achieve an additive synergistic effect of the drugs while prolonging the effect of the drug.

Siegel teaches the antipsychotic drug – haloperidol, used to treat psychotic disorders such as schizophrenia (paragraph 0032). Siegel discloses risperidone as a known antipsychotic drug (paragraphs (0009) and (0014)). While Siegel does not teach the antipsychotic drug – risperidone, for use in the invention, both of these drugs - haloperidol and risperidone are well-

known effective psychotic medications useful for the treatment of psychotic disorders and would have equivalent efficacy, as evidenced by Kino.

Kino teaches a sustained release microsphere preparation produced by combining an antipsychotic drug such as haloperidol or risperidone with polymers such as polylactic acid, polyglycolic acid or the like (see column 2, line 45 - col. 3, line 16); Claims 5 and 8. The preparation of Kino aims to improve the maintenance therapy and increase patient compliance with hydrophobic antipsychotic drugs (col. 2, lines 15-29); (col. 2, lines 5-20). Additional antipsychotic drugs are disclosed at column 2, lines 45-55.

It would have been obvious to one of ordinary skill in the art in order to employ any antipsychotic drug, particularly risperidone, such as that taught by Kino, within the delivery systems of Siegel. One would do so with a reasonable expectation of success because Kino teaches preparations with the incorporation of antipsychotic drugs such as risperidone, haloperidol and the like which are known for their therapeutic efficacy of mental conditions (i.e., schizophrenia, bipolar disorder). The preparations enable improved patient compliance and effectively provide for the treatment and therapy of mental disorders and psychotic conditions. The expected result would be an improved drug delivery system comprised of antipsychotic agents for effectively combating psychotic disorders.

5. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel et al. (US 2002/0179096) and Kino et al. (US Patent 5, 871, 778) as applied to claims 1-13, 15-20 above, and further in view of Sidman (US Patent 4, 352, 337).

Siegel does not disclose a rod shaped implant having a diameter of about 1 to 2mm, a length between about 10 and about 40 nm, or a combination thereof, however, Sidman teaches a rod-shaped implantable drug delivery device (col. 10 line 62-64 Fig 2). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to formulate the implants as taught by Siegel into the shape of rods because it would have been obvious to one of skill in the art to form the implants in a shape that is desirable for ease of administration.

Sidman further teaches that the implant has a diameter between 2-4mm(col. 22 lines 45-40).

RESPONSE TO ARGUMENTS

6. Applicant's arguments have been considered but were not found persuasive. Applicants have submitted a declaration which has been considered but is not persuasive

Applicants argue that nowhere does Sigel teach or suggest a biodegradable polymer that comprises a poly(lactide/glycolide) (PLGA) copolymer at a concentration of about 40-90% (w/w) and a drug that comprises risperidone, 9-OH-risperidone, or an active metabolite thereof at a concentration of about 10-60% w/w. Applicans' argue that Sigel relates to haloperidol loaded implant, not risperidone loaded implant.

Applicants go on to argue that although Kino describes a laundry list of active materials including risperidone, it provides no data or support for how much of each active ingredient that can be loaded into each biodegradable polymer. Therefore, at the minimum, Kino provides a general guidance for producing only a microcapsule with no expectation of success with respect to specific amount of drug for each combination of the drug and the polymer for an implant.

Applicants argue that it is well known in the art that concentrations are critical for making a polymer-based drug implant because of possible saturation and subsequent crystallization of the drug. Therefore it would be unreasonable to expect initial theoretical drug concentrations of 10% or more, without any data. In addition, a combination of a drug and a polymer may exhibit differing physiochemical properties at various concentrations, and thus one could not expect or predict whether the arrangement and/or conformation of molecules in the crystal lattice would change while combining the drug and the polymer during solvent casting or other approaches to form an implant. Therefore, an attempt to incorporate as much as 10-60% risperidone into PLA;PGA copolymer cannot be expected in view of Siegel, Kino, or any reference in the art. It would be unreasonable to expect initial theoretic drug concentrations of 10% or more due to possible saturation and subsequent crystallization of the drug.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007).

The Examiner respectfully submits in this case, the primary reference of Siegel teaches an implantable drug delivery system for long- term delivery of the antipsychotic hydrophobic drug haloperidol. Examiner agrees that Siegel does not teach an implant loaded with risperidone. Siegel does teach the claimed encapsulating polymer and the advantages to be obtained by its use. Examiner also agrees with applicant that Kino teaches many different drugs but also

specifically teach the equivalence of haloperidol and risperidone in the same context as the instant invention. Kino teaches to use the disclosed drugs in conventional amounts and therefore do not disclose data or support for how much of each drug should be loaded into an insert for use in a patient because such dosages are well known to those of ordinary skill in the art.

It would have been obvious to one of ordinary skill in the art in order to employ risperidone within the delivery systems taught by Siegel for providing a new long-acting implant for the treatment of schizophrenia, bipolar disorder, and behavior problems in people with autism. One would do so, because Kino teaches that preparations comprising PLA:PGA matrix can successfully accommodate various hydrophobic antipsychotic drugs, e.g., risperidone, haloperidol and the like, which are known for their therapeutic efficacy of mental conditions.

The argument that "Kino describes a laundry list of active materials including risperidone but provides no data or support for how much of each active ingredient can be loaded into each biodegradable polymer" was not rendered persuasive. The fact that the reference recognizes use of risperidone for the treatment of mental conditions such as schizophrenia and bipolar disorder is ample to meet Applicant's claimed limitations. With respect to the amount of biodegradable polymer, note that the implant of Siegel comprises a polylactic acid to polyglycolic acid, PLA:PGA ratio of 75:25, 50:50 and 100:0 (Para. 0023-0024, 0026; Examples 1 and 5). This range reads on, falls within and overlaps with the range of said polymer (polylactide) of 40-90% in instant Claim 1. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists (*In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934; Fed. Cir.1990).*

With respect to the amount of active ingredient that can be loaded into each biodegradable polymer matrix, the instantly claimed drug percentage/range (10-60%) is very close to (20-40%) claimed by Siegel (Para. 0023, 0024, 0026, 0038, 0039) and (25-35%) disclosed by Kino (Col. 6, Lns. 1-20, 55-65; Col. 7, Lns. 18-25) . The Examiner points out that differences in concentration will not support the patentability of subject matter encompassed by the prior art, unless there is evidence indicating such concentration is critical.

The Examiner emphasizes that Siegel and Kino disclose delivery system comprising PLA:PGA polymeric matrix and hydrophobic drug incorporated therein. It is a position of the Examiner that optimization of such a delivery system would involve variation of polymer molecular weight; polymer mixture composition; solvents; methods for incorporating a drug into the matrix and for solvent evaporation. With regard to the PLA:PGA matrix, this technique has been studied in considerable detail providing correlation between drug hydrophobicity and polymeric composition (J Biomater Sci Polym Ed. 1997;9(1):75-87; J Biomater Sci Polym Ed. 1997; 8(12):905-17; J Biomater Sci Polym Ed. 2000; 11(3):301-318; J Biomater Sci Polym Ed. 2001;12(1):21-34 as example). Further, Kino discloses the PLA:PGA microcapsules comprising risperidone prepared in dichloromethane, i.e., a good solvent for the drug (Col. 6, Lns. 1-20). Applicant utilized acetone (Para. 00210 and 00194), which is known to ease risperidone crystallization (U.S. 6,750,341). Altogether, it is a position of the Examiner that optimization of implant characteristics would be carried out by one skilled in the art via manipulative experimentation including solvent casting conditions, polymer composition and initial concentrations of drug.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable ranges or percentages of hydrophobic drug via routine/manipulative experimentation, to obtain the best possible results, as these are variable parameters attainable within the art. Risperidone and haloperidol have very close structural similarity and it is expected that they would behave in a very similar fashion. Furthermore, no unexpected or superior results have been observed in the instant amounts or ranges claimed. The prior art clearly teaches a similar formulation having similar ingredients, used for the same field of endeavor, as that desired by Applicants. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

NEW REJECTIONS- Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 8, 10-14, 16-20, and 22-25 of copending Application No. 11/195,845 (Application'845).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the Application'845 also claims an implantable, long term delivery system comprising a therapeutic drug risperidone (Claims 1, 4, 13, 16 and 29) in combination with biodegradable polylactic and polyglycolic acids in a molar ratio between 75:25, 50:50 and 100:0 (Claims 1, 13 and 25). The implant has similar length, diameter, and surface/volume ratio (Claims 10-12 and 22-24) and can be removed after treatment (Claims 2 and 14). The main difference between the instant application and the Application'845 is that the Application'845 claims a specific rod-shape of the implant structure in claim 1. While there is not a rod structure in claim 1 of the instant application, claim 13 of the instant application encompasses the rod structure.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to fluctuate the implant structure to ease incision and removal of the implant and/or to improve drug delivery. Therefore, the instant application and the Application'845 are claiming obvious variations of the same invention.

8. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, 10, 12-15, 19-23, 27-29, 32 and 34-44 of copending Application No. 11/988,137 (Application'137).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the Application'137 also claims an implantable, long term delivery system comprising a risperidone (Claims 5 and 40) or haloperidol (Claims 6 and 29) in combination with biodegradable polymers such as polylactic acid and optional polyglycolic acid in a molar ratio between 50:50 and 100:0 (Claims 1, 15, 36) and 75:25 and 100:0 (Claims 7, 22, 41). The implant has similar length, diameter, and surface/volume ratio (Claims 14, 33, 45) and can be removed after treatment (Claims 2 and 14). The main difference between the instant application and the Application'137 is that the Application'137 claims a specific rod-shape of the implant structure in claim 1.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to vary the implant shape to ease incision and removal of the implant and/or to improve drug delivery. Therefore, the instant application and the Application'137 are claiming obvious variations of the same invention.

9. Claims 1, 14, 21-23, 29, 35, 36 and 97 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 14, 21-23, 29, 35, 36 and 97 of copending Application No. 11/183232 (Application'232).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the Application'232 also claims a method of treating a nervous system disorder, such as schizophrenia and bipolar disorder (Claim 12), based on administration of a formulation that can be in the form of an implant (Claims 6-7, 30-32, and 43-45), comprising biodegradable polymers such as polylactic acid and polyglycolic acid in a molar ratio of from

about 100:0 to 50:50 (Claims, 23-26, 35-42). The implantable, long term delivery system comprises a therapeutic drug such as risperidone (Claims 16, 28, 35, 38) and haloperidol (Claims 16, 28) in combination with biodegradable polymers. The implant has similar dimensions (length, diameter) as that of the instant application (see instant claims 21-23 and claim 45 of '611). The main difference between the instant application and the Application'232 is that Application'232 does not claim a specific rod-shape of the implant structure. Furthermore, the Application '232 claims surface area to volume ratio.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to vary the implant shape to ease incision and removal of the implant and/or to improve drug delivery. Therefore, the instant application and the Application'232 are claiming obvious variations of the same invention.

CORRESPONDENCE

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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/DA/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
Art Unit 1615